

Please cancel claims 7, 10, 58-65, 121-133, 183-200, 209-219, 223-229, 233-238, 243-246, 254, 259-261, 267-270, 272, 276, 277, 282-285, 287, 292, 293, 295-297, 299, 304-308, 310, 314-320, 324-327, 329, 332-335, 337, 342-345, and 349-352 without prejudice. In addition, please amend claims 1, 15, 19, 66, 68-71, 73, 75-77, 79, 182, 201-208, 220, 231, 232, 239, 241, 247, 249, 252, 253, 256, 262, 265, 271, 274, 279, 286, 289, 294, 298, 301, 309, 312, 322, 328, 331, 336, 339-341, 347, and 353, and add new claims 358-372 to read as shown below. This listing of claims will replace all prior versions and listings of claims in the instant application:

sub B1 1. (Currently Amended) A therapeutic device, comprising a device which locally administers radiation, and a spacer, wherein said spacer comprises a polymer and a cell-cycle inhibitor.

2. (Original) The device according to claim 1 wherein said device is a radioactive stent.

3. (Original) The device according to claim 1 wherein said device is a radioactive rod.

4. (Original) The device according to claim 1 wherein said device is a radioactive disk.

5. (Original) The device according to claim 1 wherein said device is a radioactive seed.

6. (Original) The device according to claim 1 wherein said device is a radioactive suture.

7. (Cancelled)

8. (Original) The device according to claim 7 wherein said cell-cycle inhibitor is released by said polymer.

9. (Original) The device according to claim 1 wherein said radiation is released from a polymer.

10. (Cancelled)

11. (Original) The device according to claim 7 or 9 wherein said polymer is a biodegradable polymer.

12. (Currently Amended) The device according to ~~claim 7~~ claim 1 wherein said polymer comprises poly (lactic acid).

13. (Original) The device according to claim 7 wherein said polymer comprises a copolymer of poly (caprolactone) and poly (lactic acid).

14. (Original) The device according to claim 7 wherein said polymer comprises MePEG.

15. (Currently Amended) The device according to claim 1 wherein said radioactive source is selected from the group consisting of activity  $I^{125}$ ,  $Pd^{103}$ , ~~and~~  $Ir^{192}$ ,  $Co^{60}$ ,  $Cs^{137}$ , and  $Ru^{106}$ .

16. (Original) The device according to claim 1 wherein said cell-cycle inhibitor is a taxane.

17. (Original) The device according to claim 1 wherein said cell-cycle inhibitor is a topoisomerase inhibitor.

18. (Original) The device according to claim 1 wherein said cell-cycle inhibitor is an alkylating agent, anti-metabolite, or, vinca alkaloid.

19. (Currently Amended) A therapeutic device, comprising:  
a radioactive source sized to be positioned into the tissue of a patient adjacent to a site to be treated by locally administered radiation from the radioactive source; and  
a spacer comprising a cell-cycle inhibitor positioned adjacent to the radioactive source.

20. (Original) The device according to claim 19 further including a carrier member supporting the radioactive source.

21. (Original) The device according to claim 20 wherein the carrier member is a suture.

22. (Original) The device according to claim 21 wherein the radioactive source is disposed within the suture.

23. (Original) The device according to claim 22 wherein the radioactive source comprises a plurality of radioactive seeds, and the seeds are positioned at locations along a length of the suture.

24. (Original) The device according to claim 21 wherein a cell-cycle inhibitor is positioned within the suture.

25. (Original) The device according to claim 21 wherein a cell-cycle inhibitor is positioned within the suture by being absorbed by the suture prior to positioning of the suture in the tissue.

26. (Original) The device according to claim 21 wherein a cell-cycle inhibitor is carried by a carrier material positioned one of within the suture or on an outer surface of the suture, and the carrier material is a material selected to release a cell-cycle inhibitor when the suture is within the tissue.

27. (Original) The device according to claim 26 wherein the material selected for the carrier material is a polymer.

28. (Original) The device according to claim 26 wherein a cell-cycle inhibitor is carried by the carrier material by being absorbed by the carrier material prior to positioning of the suture in the tissue.

29. (Original) The device according to claim 21 wherein a cell-cycle inhibitor is carried by a carrier material positioned within the suture or on an outer surface of the suture, and the carrier material is a material selected to elute a cell-cycle inhibitor when the suture is within the tissue.

30. (Original) The device according to claim 21 wherein the suture has at least a portion of the suture comprised of a material that carries a cell-cycle inhibitor.

31. (Original) The device according to claim 21 wherein a cell-cycle inhibitor is carried by the suture, and the suture is a material selected to release a cell-cycle inhibitor when the suture is within the tissue.

32. (Original) The device according to claim 31 wherein the material selected for the carrier member is a polymer.

33. (Original) The device according to claim 31 wherein a cell-cycle inhibitor is carried by the suture by being absorbed by the suture prior to positioning of the suture in the tissue.

34. (Original) The device according to claim 21 wherein a cell-cycle inhibitor is carried by the suture, and the suture is a material selected to elute a cell-cycle inhibitor when the suture is within the tissue.

35. (Original) The device according to claim 21 wherein a cell-cycle inhibitor is positioned on an outer surface of the suture prior to positioning of the suture in the tissue.

36. (Original) The device according to claim 21 wherein the suture has an outer member positioned at least partially about an outer surface of the suture prior to positioning of the suture in the tissue, and a cell-cycle inhibitor is carried by the outer member.

37. (Original) The device according to claim 36 wherein the outer member is a coating at least partially covering the outer surface of the suture.

38. (Original) The device according to claim 37 wherein the coating is a polymeric material and a cell-cycle inhibitor is within the polymeric material.

39. (Original) The device according to claim 37 wherein the outer member is a material selected to release a cell-cycle inhibitor when the suture is within the tissue.

40. (Original) The device according to claim 39 wherein the material selected for the outer member is a polymer.

41. (Original) The device according to claim 37 wherein the outer member is a material selected to elute a cell-cycle inhibitor when the suture is within the tissue.

42. (Original) The device according to claim 21 wherein a cell-cycle inhibitor is one of chemically linked to or coated on the radioactive suture.

43. (Original) The device according to claim 19 wherein the radioactive source is a radioactive wire.

44. (Original) The device according to claim 43 wherein a cell-cycle inhibitor is positioned on an outer surface of the wire.

45. (Original) The device according to claim 43 wherein a cell-cycle inhibitor is positioned on an outer surface of the wire prior to positioning of the wire in the tissue.

46. (Original) The device according to claim 43 wherein a cell-cycle inhibitor is carried by a carrier material positioned on an outer surface of the wire, and the carrier material is a material selected to release a cell-cycle inhibitor when the wire is within the tissue.

47. (Original) The device according to claim 46 wherein the material selected for the carrier material is a polymer.

48. (Original) The device according to claim 46 wherein a cell-cycle inhibitor is carried by the carrier material by being absorbed by the carrier material prior to positioning of the wire in the tissue.

49. (Original) The device according to claim 43 wherein a cell-cycle inhibitor is carried by a carrier material positioned on an outer surface of the wire, and the carrier material is a material selected to elute a cell-cycle inhibitor when the wire is within the tissue.

50. (Original) The device according to claim 43 wherein the wire has an outer member positioned at least partially about an outer surface of the wire prior to positioning of the wire in the tissue, and a cell-cycle inhibitor is carried by the outer member.

51. (Original) The device according to claim 50 wherein the outer member is a coating at least partially covering the outer surface of the wire.

52. (Original) The device according to claim 51 wherein the coating is a polymeric material and a cell-cycle inhibitor is within the polymeric material.

53. (Original) The device according to claim 51 wherein the outer member is a material selected to release a cell-cycle inhibitor when the wire is within the tissue.

54. (Original) The device according to claim 53 wherein the material selected for the outer member is a polymer.

55. (Original) The device according to claim 50 wherein the outer member is a material selected to release a cell-cycle inhibitor when the wire is within the tissue.

56. (Original) The device according to claim 43 wherein a cell-cycle inhibitor is one of chemically linked to or coated on the wire.

57. (Original) The device according to claim 19 wherein the radioactive source comprises a plurality of radioactive seeds.

58. – 65. (Cancelled)

66. (Currently Amended) The device according to ~~claim 65~~ claim 19 wherein the spacer is a material selected to release a cell-cycle inhibitor when within the tissue.

67. (Original) The device according to claim 66 wherein the material selected for the spacer is a polymer.

68. (Currently Amended) The device according to ~~claim 65~~ claim 19 wherein a cell-cycle inhibitor is carried by the spacer by being absorbed by the spacer prior to positioning of the spacer in the tissue.

69. (Currently Amended) The device according to ~~claim 65~~ claim 19 wherein the spacer is a material selected to elute a cell-cycle inhibitor when within the tissue.

70. (Currently Amended) The device according to ~~claim 64~~ claim 19 wherein the spacer is a polymeric material and a cell-cycle inhibitor is within the polymeric material.

71. (Currently Amended) The device according to ~~claim 64~~ claim 19 wherein a cell-cycle inhibitor is positioned on an outer surface of the spacer.

72. (Original) The device according to claim 71 wherein a cell-cycle inhibitor is positioned on the outer surface of the spacer prior to positioning of the spacer in the tissue.

73. (Currently Amended) The device according to ~~claim 64~~ claim 19 wherein a cell-cycle inhibitor is carried by a carrier material positioned on an outer surface of the spacer, and the carrier material is a material selected to elute a cell-cycle inhibitor when the spacer ~~are~~ is within the tissue.

74. (Original) The device according to claim 73 wherein a cell-cycle inhibitor is carried by the carrier material by being absorbed by the carrier material prior to positioning of the spacer in the tissue.

75. (Currently Amended) The device according to ~~claim 64~~ claim 19 wherein the seeds and the spacers positioned between the seeds are sized to be received in a catheter for insertion into the tissue.



76. (Currently Amended) The device according to ~~claim 64~~ claim 19 wherein the spacers are elongated with a length and positioned with a lengthwise orientation extending between the adjacent seeds between which positioned, and the spacer length is selected to position and hold the seeds within the tissue in a desired spatial pattern based upon the radiation pattern desired to be administered to the site to be treated.

77. (Currently Amended) The device according to ~~claim 57~~ claim 57 further including a spacer positioned between adjacent ones of the plurality of radioactive seeds, the spacers both holding the adjacent seeds spaced apart while in the tissue and holding the plurality of seeds together as part of a continuous thread while being positioned in the tissue.

78. (Original) The device according to ~~claim 77~~ claim 77 wherein the spacers are formed from a spacer material having a liquid phase and a solid phase, the spacers being formed using the spacer material in the liquid phase immediately prior to the time of positioning of the seeds into the tissue by placing the liquid phase spacer material between adjacent ones of the seeds and then allowing the spacer material to change to the solid phase to form the continuous thread.

79. (Currently Amended) The device according to ~~claim 57~~ claim 57 further including a spacer positioned between adjacent ones of the plurality of radioactive seeds, the spacers holding the adjacent seeds spaced apart while in the tissue, the spacers being a spacer material having a liquid phase and a solid phase, the spacers being formed using the spacer material in the liquid phase immediately prior to the time of positioning of the seeds into the tissue by placing the liquid phase spacer material between adjacent ones of the seeds and then allowing the spacer material to change to the solid phase prior to positioning of the spacers in the tissue.

80. (Original) The device according to ~~claim 79~~ claim 79 for use with a catheter, wherein the seeds are positioned in the catheter in spaced apart relation and the spacer material in the liquid phase is placed between adjacent ones of the seeds and then allowed to change to the solid phase, after changing to the solid phase and without removing the seeds and the spacers

from the catheter, the seeds and the spacers being positioned in the catheter in a molded state ready for positioning in the tissue using the catheter.

81. (Original) The device according to claim 80 wherein after the spacer material has been allowed to change to the solid phase, the seeds and the spacers are in the form of a continuous thread holding the plurality of seeds together for positioning in the tissue and holding the adjacent seeds spaced apart while in the tissue.

82. (Original) The device according to claim 80 wherein the spacer material is in the liquid phase when heated to a liquid phase temperature above a body temperature of the patient, and in the solid phase when allowed to cool to a solid phase temperature below the liquid phase temperature.

83. (Original) The device according to claim 57 wherein a cell-cycle inhibitor is one of chemically linked to or coated on the seeds.

84. (Original) The device according to claim 19 wherein the radioactive source comprises at least one radioactive seed and the seed has an outer member positioned at least partially about an outer surface of the seed prior to positioning of the seed in the tissue, and wherein a cell-cycle inhibitor is carried by the outer member.

85. (Original) The device according to claim 84 wherein the outer member is a coating at least partially covering the outer surface of the seed.

86. (Original) The device according to claim 85 wherein the coating is a polymeric material and a cell-cycle inhibitor is within the polymeric material.

87. (Original) The device according to claim 84 wherein the outer member is a material selected to release a cell-cycle inhibitor when the wire is within the tissue.

88. (Original) The device according to claim 87 wherein the material selected for the outer member is a polymer.

89. (Original) The device according to claim 84 wherein the outer member is a material selected to elute a cell-cycle inhibitor when the wire is within the tissue.

90. (Original) The device according to claim 84 wherein a cell-cycle inhibitor is carried by the outer member by being absorbed by the outer member prior to positioning of the seeds in the tissue.

91. (Original) The device according to claim 19 wherein the radioactive source comprises at least one radioactive seed, and wherein a cell-cycle inhibitor is one of chemically linked to or coated on the seed.

92. (Original) A therapeutic device, comprising:  
a radioactive source sized to be positioned into a pre-existing or created body cavity of a patient adjacent to a site to be treated by locally administered radiation from the radioactive source; and  
a cell-cycle inhibitor positioned adjacent to the radioactive source.

93. (Original) The device according to claim 92 wherein the radioactive source is a radioactive stent.

94. (Original) The device according to claim 93 wherein the radioactive source is a radioactive film.

95. (Original) The device according to claim 93 wherein the stent is formed of a carrier material and the carrier material carries a cell-cycle inhibitor, the carrier material being a material selected to release a cell-cycle inhibitor when the stent is within the body cavity.

96. (Original) The device according to claim 95 wherein the carrier material is a polymer.

97. (Original) The device according to claim 92 further including a stent sized to be positioned in the body cavity, the stent being formed of a carrier material which carries a cell-cycle inhibitor, the carrier material being a material selected to release a cell-cycle inhibitor when the stent is within the body cavity.

98. (Original) The device according to claim 97 wherein the carrier material is a polymer.

99. (Original) The device according to claim 93 wherein a cell-cycle inhibitor is positioned on an outer surface of the stent.

100. (Original) The device according to claim 93 wherein a cell-cycle inhibitor is positioned on an outer surface of the stent prior to positioning of the stent in the body cavity.

101. (Original) The device according to claim 93 wherein a cell-cycle inhibitor is carried by a carrier material positioned on an outer surface of the stent, and the carrier material is a material selected to release a cell-cycle inhibitor when the stent is within the body cavity.

102. (Original) The device according to claim 93 wherein the material selected for the carrier material is a polymer.

103. (Original) The device according to claim 101 wherein a cell-cycle inhibitor is carried by the carrier material by being absorbed by the carrier material prior to positioning of the stent in the body cavity.

104. (Original) The device according to claim 93 wherein a cell-cycle inhibitor is carried by a carrier material positioned on an outer surface of the stent, and the carrier material is a material selected to elute a cell-cycle inhibitor when the stent is within the body cavity.

105. (Original) The device according to claim 93 wherein the stent has an outer member positioned at least partially about an outer surface of the stent prior to positioning of the stent in the body cavity, and a cell-cycle inhibitor is carried by the outer member.

106. (Original) The device according to claim 105 wherein the outer member is a coating at least partially covering the outer surface of the stent.

107. (Original) The device according to claim 106 wherein the coating is a polymeric material and a cell-cycle inhibitor is within the polymeric material.

108. (Original) The device according to claim 105 wherein the outer member is a material selected to release a cell-cycle inhibitor when the stent is within the body cavity.

109. (Original) The device according to claim 108 wherein the material selected for the outer member is a polymer.

110. (Original) The device according to claim 108 wherein a cell-cycle inhibitor is carried by the outer member by being absorbed by the outer member prior to positioning of the stent in the body cavity.

111. (Original) The device according to claim 105 wherein the outer member is a material selected to elute a cell-cycle inhibitor when the stent is within the body cavity.

112. (Original) The device according to claim 93 wherein a cell-cycle inhibitor is one of chemically linked to or coated on the stent.

113. (Original) The device according to claim 92 wherein the radioactive source comprises a plurality of radioactive seeds.

114. (Original) The device according to claim 113 wherein a cell-cycle inhibitor is positioned on an outer surface of the seeds.

115. (Original) The device according to claim 113 wherein a cell-cycle inhibitor is positioned on an outer surface of the seeds prior to positioning of the seeds in the body cavity.

116. (Original) The device according to claim 113 wherein a cell-cycle inhibitor is carried by a carrier material positioned on an outer surface of each of the seeds, and the carrier material is a material selected to release a cell-cycle inhibitor when the seeds are in the body cavity.

117. (Original) The device according to claim 116 wherein the material selected for the carrier member is a polymer.

118. (Original) The device according to claim 116 wherein a cell-cycle inhibitor is carried by the carrier material by being absorbed by the carrier material prior to positioning of the seeds in the body cavity.

119. (Original) The device according to claim 113 wherein a cell-cycle inhibitor is carried by a carrier material positioned on an outer surface of each of the seeds, and the carrier material is a material selected to elute a cell-cycle inhibitor when the seeds are in the body cavity.

120. (Original) The device according to claim 113 wherein a cell-cycle inhibitor is one of chemically linked to or coated on the seeds.

121. - 133. (Cancelled)

134. (Original) A therapeutic device, comprising:  
a radioactive source;  
a body contact member carrying the radioactive source, the body contact member being sized to be positioned against a pre-existing or created surface site of a patient's body to be treated by locally administered radiation from the radioactive source; and  
a cell-cycle inhibitor.

135. (Original) The device according to claim 134 wherein the body contact member is a sheet.

136. (Original) The device according to claim 134 for use when the site of the patient's body to be treated is curved, wherein the body contact member is sufficiently flexible to be bent to at least partially approximate the curve of the site.

137. (Original) The device according to claim 134 for use when the site of the patient's body to be treated is curved, wherein the body contact member is contoured to at least partially approximate the curve of the site.

138. (Original) The device according to claim 137 wherein the body contact member is molded to the curve of the site.

139. (Original) The device according to claim 134 wherein the radioactive source comprises a plurality of radioactive wires.

140. (Original) The device according to claim 139 wherein the radioactive wires are arranged about the body contact member in a desired spatial pattern based upon a radiation pattern desired to be administered to the site to be treated.

141. (Original) The device according to claim 139 wherein the radioactive wires are embedded in the body contact member.

142. (Original) The device according to claim 139 wherein the body contact member includes a plurality of spaced apart recesses sized to receive at least partially therein the radioactive wires.

143. (Original) The device according to claim 142 further including a retainer member extending over at least a portion of the recesses and retaining the radioactive wires in the recesses.

144. (Original) The device according to claim 143 wherein the retaining member is a sheet extending over at least a portion of the body contact member and closing at least the portion of the recesses over which the sheet extends.

145. (Original) The device according to claim 142 wherein the body contact member is a flexible film.

146. (Original) The device according to claim 145 wherein the film is scored to form the recesses therein.

147. (Original) The device according to claim 139 wherein the body contact member is a first flexible film and the radioactive wires are one of embedded in, resident on, or retained upon the first film.



148. (Original) The device according to claim 147 wherein the first film is selected of a material which can be cut with one of a scalpel or scissors to a desired shape.

149. (Original) The device according to claim 147 wherein the radioactive wires are positioned in a desired spatial pattern with respect to the first film based upon a radiation pattern desired to be administered to the site to be treated

150. (Original) The device according to claim 147 further including a second flexible film extending over at least a portion of the first film with the radioactive wires being retained between the first and second films.

151. (Original) The device according to claim 150 wherein the first film includes a plurality of spaced apart recesses sized to receive at least partially therein the radioactive wires, and the second film at least partially closes the recesses to retain the radioactive wires therein.

152. (Original) The device according to claim 139 wherein the body contact member is a flexible film with a plurality of spaced apart recesses sized to receive at least partially therein the radioactive wires, and the device further includes at least one retainer member positioned to retain the radioactive wires within the recesses.

153. (Original) The device according to claim 134 wherein the radioactive source comprises a plurality of radioactive seeds.

154. (Original) The device according to claim 153 wherein the radioactive seeds are arranged about the body contact member in a desired spatial pattern based upon a radiation pattern desired to be administered to the site to be treated.(Original)

155. (Original) The device according to claim 153 wherein the radioactive seeds are mbedded in the body contact member.

156. (Original) The device according to claim 153 wherein the body contact member includes a plurality of spaced apart recesses sized to receive at least partially therein the radioactive seeds.

157. (Original) The device according to claim 156 further including a retainer member extending over at least a portion of the recesses and retaining the radioactive seeds in the recesses.

158. (Original) The device according to claim 157 wherein the retaining member is a sheet extending over at least a portion of the body contact member and closing at least the portion of the recesses over which the sheet extends.

159. (Original) The device according to claim 156 wherein the body contact member is a flexible film.

160. (Original) The device according to claim 159 wherein the film is scored to form the recesses therein.

161. (Original) The device according to claim 153 wherein the body contact member is a first flexible film and the radioactive seeds are one of embedded in, resident on, or retained upon the first film.

162. (Original) The device according to claim 161 wherein the first film is selected of a material which can be cut with one of a scalpel or scissors to a desired shape.

163. (Original) The device according to claim 161 wherein the radioactive seeds are positioned in a desired spatial pattern with respect to the first film based upon a radiation pattern desired to be administered to the site to be treated.

164. (Original) The device according to claim 161 further including a second flexible film extending over at least a portion of the first film with the radioactive seeds being retained between the first and second films.

165. (Original) The device according to claim 164 wherein the first film includes a plurality of spaced apart recesses sized to receive at least partially therein the radioactive seeds, and the second film at least partially closes the recesses to retain the radioactive seeds therein.

166. (Original) The device according to claim 153 wherein the body contact member is a flexible film with a plurality of spaced apart recesses sized to receive at least partially therein the radioactive seeds, and the device further includes at least one retainer member positioned to retain the radioactive seeds within the recesses.

167. (Original) The device according to claim 134 wherein a cell-cycle inhibitor is positioned on an outer surface of the body contact member.

168. (Original) The device according to claim 134 wherein the body contact member includes a carrier material which carries a cell-cycle inhibitor, the carrier material being selected to release a cell-cycle inhibitor when the body contact member is against the site to be treated.

169. (Original) The device according to claim 134 wherein the body contact member includes at least one recess sized to receive at least partially therein the radioactive source.

170. (Original) The device according to claim 169 further including a retainer member extending over at least a portion of the recess and retaining the radioactive source in the recess.

171. (Original) The device according to claim 170 wherein the retaining member is a sheet extending over at least a portion of the body contact member and closing at least the portion of the recess over which the sheet extends.

172. (Original) The device according to claim 134 wherein the body contact member is a flexible film.

173. (Original) The device according to claim 172 wherein the film is scored to form at least one recess therein to receive at least partially therein the radioactive source.

174. (Original) The device according to claim 172 wherein the film has the radioactive sources at least one of embedded in, resident on, or retained upon the film.

175. (Original) The device according to claim 174 wherein the radioactive source is positioned with a desired spatial pattern with respect to the film based upon a radiation pattern desired to be administered to the site to be treated

176. (Original) The device according to claim 134 wherein the body contact member is formed at least in part from a carrier material which carries a cell-cycle inhibitor, the carrier material being selected to release a cell-cycle inhibitor when the body contact member is against the site to be treated.

177. (Original) The device according to claim 176 wherein the material selected for the carrier member is a polymer.

178. (Original) The device according to claim 176 wherein a cell-cycle inhibitor is carried by the carrier material by being absorbed by the carrier material prior to the body contact member being positioned against the site to be treated.

179. (Original) The device according to claim 134 wherein the body contact member is formed at least in part from a carrier material which carries a cell-cycle inhibitor, the carrier material being selected to elute a cell-cycle inhibitor when the body contact member is against the site to be treated.

180. (Original) A therapeutic device, comprising:  
a radioactive source;  
a body contact material carrying the radioactive source, the body contact member being applied to a pre-existing or created surface site of a patient's body to be treated by locally administered radiation from the radioactive source; and  
a cell-cycle inhibitor.

181. (Original) The device of claim 180 wherein the body contact material is formed from one of a paste, gel, film or spray applied to the site to be treated.

182. (Currently Amended) A method for treating cellular proliferation, comprising administering to a patient a therapeutic device according to any one of ~~claims 1 to 18~~ claims 1, 5, 12, 15, 16, and 17.

183. – 200. (Cancelled)

201. (Currently Amended) The method according to claim 182 ~~or 183~~ wherein said cellular proliferation is due to cancer.

202. (Currently Amended) The method according to claim 182 ~~or 183~~ wherein said cellular proliferation is due to stenosis or restenosis.

203. (Currently Amended) The method according to claim 182 ~~or 183~~ wherein said cellular proliferation is due to an adhesion.

204. (Currently Amended) The method according to claim 182 ~~or 183~~ wherein said cellular proliferation is due to vascular disease.

205. (Currently Amended) The method according to claim 182 ~~or 183~~ wherein said cellular proliferation is due to arthritis.

206. (Currently Amended) The method according to claim 182 ~~or 183~~ wherein said cell-cycle inhibitor or radioactive source is administered close to the surface of the body.

207. (Currently Amended) The method according to claim 182 ~~or 183~~ wherein said cell-cycle inhibitor or radioactive source is administered within a body cavity.

208. (Currently Amended) The method according to claim 182 ~~or 183~~ wherein said cell-cycle inhibitor or radioactive source is administered directly into a body tissue.

209. - 219. (Cancelled)

220. (Currently Amended) A method for treating a hyperproliferative disease of the prostate, comprising administering to the prostate a therapeutic device comprising cell-cycle inhibitor and a radioactive source, and a spacer containing a cell cycle inhibitor, such that said hyperproliferative disease of the prostate is treated.

221. (Original) The method according to claim 220 wherein said hyperproliferative disease of the prostate is prostate cancer.

222. (Original) The method according to claim 220 wherein said hyperproliferative disease of the prostate is benign prostatic hypertrophy.

223. - 229 (Cancelled)

230. (Original) The method according to claim 220 wherein said cell-cycle inhibitor comprises at least one taxane, topoisomerase inhibitor, vinca alkaloid, alkalating agent, or estramustine.

231. (Currently Amended) A method for treating a hyperproliferative disease of the anorectum, comprising administering to the anorectum a therapeutic device comprising cell cycle inhibitor and a radioactive source, and a spacer containing a cell cycle inhibitor, such that said hyperproliferative disease of the anorectum is treated.

232. (Currently Amended) The method according to claim 231 wherein said ~~cell cycle inhibitor~~ therapeutic device is administered to the rectal mucosa.

233. - 238 (Cancelled)

239. (Currently Amended) The method according to claim 231 wherein said ~~cell cycle inhibitor~~ therapeutic device is injected interstitially.

240. (Original) The method according to claim 231 wherein said cell-cycle inhibitor comprises at least one taxane, platinum, topoisomerase inhibitor, alkalating agent, mitomycin, or leucovorine.

241. (Currently Amended) A method for treating a hyperproliferative disease of the bladder or urinary tract, comprising administering to the bladder or urinary tract a therapeutic device comprising cell cycle inhibitor and a radioactive source, and a spacer containing a cell cycle inhibitor, such that said hyperproliferative disease is treated.

242. (Original) The method according to claim 241 wherein said hyperproliferative disease is bladder cancer.

243. - 246. (Cancelled)

247. (Currently Amended) The method according to claim 241 wherein said ~~cell-cycle inhibitor~~ therapeutic device is injected interstitially.

248. (Original) The method according to claim 241 wherein said cell-cycle inhibitor comprises at least one taxane, ethyleneimine, anthracyclines, antimetabolites, vinca alkaloids, platinum or mitomycin.

249. (Currently Amended) A method for treating a hyperproliferative disease of the eye, comprising administering to the eye a therapeutic device comprising cell-cycle inhibitor and a radioactive source, and a spacer containing a cell cycle inhibitor, such that said hyperproliferative disease is treated.

250. (Original) The method according to claim 249 wherein said hyperproliferative disease of the eye is uveal melanoma.

251. (Original) The method according to claim 249 wherein said hyperproliferative disease of the eye is retinoblastoma.

252. (Currently Amended) The method according to claim 249 wherein said ~~cell-cycle inhibitor and radioactive source~~ therapeutic device is administered via a surface eye mold.

253. (Currently Amended) The method according to claim 249 wherein said ~~cell-cycle inhibitor~~ therapeutic device is injected intravitreally, or administered via a shunt.

254. (Cancelled)

255. (Original) The method according to claim 249 wherein said cell-cycle inhibitor comprises at least one taxane, vinca alkaloid, alkylating agent, anthracycline, platinum, nitrogen mustard or topoisomerase inhibitor.



256. (Currently Amended) A method for treating a hyperproliferative disease of the brain, comprising administering to the brain a therapeutic device comprising cell-cycle inhibitor and a radioactive source, and a spacer containing a cell cycle inhibitor, such that said hyperproliferative disease is treated.

257. (Original) The method according to claim 256 wherein said hyperproliferative disease of the brain is a malignant glioma.

258. (Original) The method according to claim 256 wherein said hyperproliferative disease of the brain is an astrocytoma.

259. - 261

262. (Currently Amended) The method according to claim 256 wherein said cell cycle inhibitor therapeutic device is injected interstitially.

263. (Original) The method according to claim 256 wherein said cell cycle inhibitor is administered in a paste, film, or spray.

264. (Original) The method according to claim 256 wherein said cell-cycle inhibitor comprises at least one taxane, nitrosurea, tetrazine, vinca alkaloid, platinum, topoisomerase inhibitor, antimetabolites, or leucovorin.

265. (Currently Amended) A method for treating a hyperproliferative disease of the breast, comprising administering to the breast a therapeutic device comprising cell-cycle inhibitor and a radioactive source, and a spacer containing a cell cycle inhibitor, such that said hyperproliferative disease of the breast is treated.

266. (Original) The method according to claim 265 wherein said hyperproliferative disease of the breast is breast cancer.

267. – 270.

271. (Currently Amended) The method according to claim 265 wherein said ~~cell cycle inhibitor~~ therapeutic device is injected interstitially.

272. (Cancelled)

273. (Original) The method according to claim 265 wherein said cell-cycle inhibitor comprises at least one taxane, anthracycline, alkylating agent, antimetabolite, vinca alkaloid, platinum, nitrogen mustard, gemcitabine, or mitomycin.

274. (Currently Amended) A method for treating a hyperproliferative disease of the esophagus, comprising administering to the esophagus a therapeutic device comprising cell cycle inhibitor and a radioactive source, and a spacer containing a cell cycle inhibitor, such that said hyperproliferative disease is treated.

275. (Original) The method according to claim 274 wherein said hyperproliferative disease of the esophagus is esophageal cancer.

276., 277. (Cancelled)

278. (Original) The method according to claim 274 wherein said cell-cycle inhibitor comprises at least one taxane, alkylating agent, platinum, or mitomycin.

279. (Currently Amended) A method for treating a hyperproliferative disease of the genital tract, comprising administering to the genital tract a therapeutic device comprising cell cycle inhibitor and a radioactive source, and a spacer containing a cell cycle inhibitor, such that said hyperproliferative disease is treated.

280. (Original) The method according to claim 279 wherein said hyperproliferative disease of the genital tract is penile cancer.

281. (Original) The method according to claim 279 wherein said hyperproliferative disease of the genital tract is vaginal cancer.

282. – 285. (Cancelled)

286. (Currently Amended) The method according to claim 279 wherein said ~~cell cycle inhibitor~~ therapeutic device is administered interstitially.

287. (Cancelled)

288. (Original) The method according to claim 279 wherein said cell-cycle inhibitor comprises at least one taxane, vinca alkaloid, antimetabolite, platinum or, alkylating agent.

289. (Currently Amended) A method for treating a hyperproliferative disease of the uterus or cervix, comprising administering to the uterus or cervix a therapeutic device comprising cell cycle inhibitor and a radioactive source, and a spacer containing a cell cycle inhibitor, such that said hyperproliferative disease is treated.

290. (Original) The method according to claim 289 wherein said hyperproliferative disease is endometrial cancer.

291. (Original) The method according to claim 289 wherein said hyperproliferative disease is cervical cancer.

292., 293. (Cancelled)

294. (Currently Amended) The method according to claim 289 wherein said ~~cell cycle inhibitor therapeutic device~~ is administered to the surface of the cervix or endometrium.

295. - 297. (Cancelled)

298. (Currently Amended) The method according to claim 289 wherein said ~~cell cycle inhibitor therapeutic device~~ is injected interstitially.

299. (Cancelled)

300. (Original) The method according to claim 289 wherein said cell-cycle inhibitor comprises at least one taxane, platinum, alkylating agent, nitrogen mustard, topoisomerase inhibitor, anthracycline, or estramustine.

301. (Currently Amended) A method for treating a hyperproliferative disease of the liver or bile duct, comprising administering to the liver or bile duct a therapeutic device comprising cell cycle inhibitor and a radioactive source, and a spacer containing a cell cycle inhibitor, such that said hyperproliferative disease is treated.

302. (Original) The method according to claim 301 wherein said hyperproliferative disease is liver cancer.

303. (Original) The method according to claim 301 wherein said hyperproliferative disease is a biliary tumor.

304. - 308 (Cancelled)

309. (Currently Amended) The method according to claim 301 wherein said ~~cell cycle inhibitor therapeutic device is delivered through a drug delivery balloon or catheter, or~~ injected interstitially.

310. (Cancelled)

311. (Original) The method according to claim 301 wherein said cell-cycle inhibitor comprises at least one taxane, anthracycline, platinum, alkylating agent, gemcitabine, mitomycin, or floxuridine.

312. (Currently Amended) A method for treating a hyperproliferative disease of the lung, comprising administering to the lung a therapeutic device comprising cell-cycle inhibitor and a radioactive source, and a spacer containing a cell cycle inhibitor, such that said hyperproliferative disease is treated.

313. (Original) The method according to claim 312 wherein said hyperproliferative disease is lung cancer.

314. – 320. (Cancelled)

321. (Original) The method according to claim 312 wherein said cell-cycle inhibitor comprises at least one taxane, topoisomerase inhibitor, vinca alkaloid, platinum, alkylating agent, anthracycline, nitrogen mustard, antimetabolite, nitrosurea, mitomycin, or gemcitabine.

322. (Currently Amended) A method for treating a hyperproliferative disease of the pancreas, comprising administering to the pancreas a therapeutic device comprising cell-cycle inhibitor and a radioactive source, and a spacer containing a cell cycle inhibitor, such that said hyperproliferative disease is treated.

323. (Original) The method according to claim 322 wherein said hyperproliferative disease is pancreatic cancer.

324. – 327. (Cancelled)

328. (Currently Amended) The method according to claim 322 wherein said ~~cell cycle inhibitor~~ therapeutic device is administered interstitially.

329. (Cancelled)

330. (Original) The method according to claim 322 wherein said cell-cycle inhibitor comprises at least one taxane, anthracycline, nitrogen mustard, tetrazine, platinum, antimetabolite, or vinca alkaloid.

331. (Currently Amended) A method for treating soft-tissue sarcomas, comprising administering to a soft-tissue sarcoma a therapeutic device comprising cell cycle inhibitor and a radioactive source, and a spacer containing a cell cycle inhibitor, such that sarcoma is treated.

332. – 335. (Cancelled)

336. (Currently Amended) The method according to claim 331 wherein said ~~cell cycle inhibitor~~ therapeutic device is administered interstitially.

337. (Cancelled)

338. (Original) The method according to claim 331 wherein said cell-cycle inhibitor comprises at least one taxane, anthracycline, nitrogen mustard, tetrazine, platinum, antimetabolite, or vinca alkaloid.

339. (Currently Amended) A method for treating a hyperproliferative disease of the skin, comprising administering to the skin a therapeutic device comprising cell-cycle inhibitor and a radioactive source, and a spacer containing a cell cycle inhibitor, such that said hyperproliferative is treated.

340. (Currently Amended) The method according to claim 339 wherein said cell-cycle inhibitor-therapeutic device is administered topically, subcutaneously, or intradermally.

341. (Currently Amended) The method according to claim 339 wherein said cell-cycle inhibitor-therapeutic device is administered via a surface mold, or via a transdermal patch.

342. - 345. (Cancelled)

346. (Original) The method according to claim 339 wherein said cell-cycle inhibitor comprises at least one taxane, alkylating agent, tetrazine, or nitrosurea.

347. (Currently Amended) A method for treating a hyperproliferative disease of the head or neck, comprising administering to the head or neck a therapeutic device comprising cell-cycle inhibitor and a radioactive source, and a spacer containing a cell cycle inhibitor, such that said hyperproliferative disease is treated.

348. (Original) The method according to claim 347 wherein said hyperproliferative disease is a tumor of the tongue, mouth, lip, or, nasopharynx.

349. - 352. (Cancelled)

353. (Currently Amended) The method according to claim 347 wherein said cell-cycle inhibitor-therapeutic device is administered interstitially.

354. (Original) The method according to claim 347 wherein said cell-cycle inhibitor comprises at least one polypeptide, taxane, antimetabolite, platinum, alkylating agent, nitrogen mustard, anthracycline, or vinca alkaloid.

355. - 357. (Withdrawn)

358. (New) The device according to claim 1 wherein said cell-cycle inhibitor comprises at least one taxane, anthracycline, topoisomerase inhibitor, vinca alkaloid, alkylating agent, antimetabolite, platinum, nitrogen mustard, gemcitabine, mitomycin, or estramustine.

359. (New) The device according to claim 1 or claim 19 wherein said cell-cycle inhibitor comprises paclitaxel, or an analogue or derivative thereof.

360. (New) The device according to claim 1 wherein said spacer is positioned between adjacent ones of the plurality of radioactive seeds, the spacers both holding the adjacent seeds spaced apart and holding the plurality of seeds together as part of a continuous thread.

361. (New) The method according to claim 220 wherein the spacers and adjacent seeds are sized to be received in a catheter for insertion into the tissue.

362. (New) The method according to claim 220 wherein the radioactive source comprises a plurality of radioactive seeds.

363. (New) The method according to claim 220 wherein said polymer comprises poly (lactic acid).

364. (New) The method according to claim 220 wherein said cell-cycle inhibitor comprises paclitaxel, or an analogue or derivative thereof.



365. (New) The method according to claim 220 wherein said radioactive source is selected from the group consisting of activity  $I^{125}$ ,  $Pd^{103}$ ,  $Ir^{192}$ ,  $Co^{60}$ ,  $Cs^{137}$ , and  $Ru^{106}$ .

366. (New) The method according to claim 220 wherein said spacer is positioned between adjacent ones of the plurality of radioactive seeds, the spacers both holding the adjacent seeds spaced apart while in the tissue and holding the plurality of seeds together as part of a continuous thread while being positioned in the tissue.

367. (New) The method according to claim 265 wherein the spacers and adjacent seeds are sized to be received in a catheter for insertion into the tissue.

368. (New) The method according to claim 265 wherein the radioactive source comprises a plurality of radioactive seeds.

369. (New) The method according to claim 265 wherein said polymer comprises poly (lactic acid).

370. (New) The method according to claim 265 wherein said radioactive source is selected from the group consisting of activity  $I^{125}$ ,  $Pd^{103}$ ,  $Ir^{192}$ ,  $Co^{60}$ ,  $Cs^{137}$ , and  $Ru^{106}$ .

371. (New) The method according to claim 265 wherein said cell-cycle inhibitor comprises paclitaxel, or an analogue or derivative thereof.

372. (New) The method according to claim 265 wherein said spacer is positioned between adjacent ones of the plurality of radioactive seeds, the spacers both holding the adjacent seeds spaced apart while in the tissue and holding the plurality of seeds together as part of a continuous thread while being positioned in the tissue.